UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:22-cv-05326-RGK-MARx	Date	June 29, 2023
Title	***Sandoz Inc. v. Amgen Inc., et al.***		

Present: The Honorable	R. GARY KLAUSNER, UNITED STATES DISTRICT JUDGE	
Joseph Remigio	Not Reported	N/A
Deputy Clerk	Court Reporter / Recorder	Tape No.
Attorneys Present for Plaintiff:	Attorneys Present for Defendant:	
Not Present	Not Present	

Proceedings: **(IN CHAMBERS) Order Re: Defendant's Motion for Summary Judgment [100]**

I. INTRODUCTION

On August 1, 2022, Sandoz, Inc. ("Plaintiff") filed a Complaint against Amgen, Inc. ("Defendant"), alleging: (1) false advertising under the Lanham Act, 15 U.S.C. § 1125(a); (2) false advertising under Cal. Bus. & Prof. Code §§ 17500, *et seq.*; and (3) unfair competition under Cal. Bus. & Prof. Code § 17200. (ECF No. 1.) Presently before the Court is Defendant's Motion for Summary Judgment. (ECF No. 100.) For the following reasons, the Court **DENIES** Defendant's Motion.

II. FACTUAL BACKGROUND

The following facts are uncontroverted unless otherwise stated:

A. The Pegfilgrastim Market

Chemotherapy is a common treatment prescribed to cancer patients. (Akrotirianakis Decl. (hereinafter "Akro. Decl."), Ex. B at 44, 46, ECF No. 116-3.) While chemotherapy works by killing cancer cells, it has the unintended effect of reducing a patient's neutrophils, which are a type of white blood cell that helps the body fight infections. (*Id.*) This in turn makes patients susceptible to febrile neutropenia ("FN"), a dangerous, life-threatening infection. (Akro. Decl., Ex. A at 20 § 14.1, ECF No. 116-2.)

In 2002, Defendant introduced Neulasta, a pegfilgrastim injection that would decrease the incidence of FN by stimulating production of neutrophils. (Akro. Decl., Ex. C at 57, ECF No. 116-4.) Neulasta was administered via prefilled syringe ("PFS"). (Compl. ¶ 37.) Thanks to its patents, Defendant

enjoyed a temporary exclusivity period through which Defendant was the sole seller of pegfilgrastim injections until 2015, when its last patents expired. (Benoff Decl. Ex. A at 5, ECF No. 115-4.) Shortly before that period ended, in 2014, Defendant introduced Onpro, a new method for delivering Neulasta through an "on-body injector." (Akro. Decl., Ex. C at 60, § 2.4.) With Onpro, patients could receive timed pegfilgrastim injections the day after chemotherapy without returning to the healthcare facility. (*Id.*)

After Defendant's patents expired, competing pharmaceutical companies raced to develop and market pegfilgrastim biosimilars[1]. The first pegfilgrastim biosimilar hit the market in November 2018, and would ultimately be followed by five others, including Plaintiff's Ziextenzo in November 2019. (Akro. Decl., Ex. D at 83–84, ECF No. 116-5.)

B. Defendant's Onpro Advertising Campaign

A few months after Plaintiff launched Ziextenzo, Defendant launched a multi-million-dollar ad campaign to promote Onpro. (Benoff Decl., Ex. I at 173–94, ECF No. 115-12; Ex. J at 200–02, ECF No. 115-13.) These ads claimed that "Pegfilgrastim PFS resulted in a significantly higher risk of FN vs. Onpro" and "[w]ith PFS, FN incidence increased by 31% vs Onpro." (Benoff Decl., Ex. G at 146–47, ECF No. 115-10; Ex. H at 157–68, ECF No. 115-11.) These ads were based on an observational study Defendant conducted itself, in an effort to remain competitive with the emerging biosimilar market. (Benoff Decl., Ex. D at 97, ECF No. 115-7; Ex. E at 123, ECF No. 115-8; Ex. F at 136, ECF No. 115-9; Ex. KK at 746, 771–72, ECF No. 115-40.)

However, doubts about the validity of the study and Defendant's conclusions quickly emerged. The FDA, independent reviews at scientific journals, and even some of Defendant's own employees criticized the advertising claims as unsupported and misleading. (Benoff Decl., Ex. O at 271–75, ECF No. 115-18; Ex. P at 278–79, ECF No. 115-19; Ex. Q at 281, ECF No. 115-20; Ex. S at 287–94, ECF No. 115-22.) In response, Defendant conducted a second study to bolster its claims. (*See* Benoff Decl. Ex. Z at 337–38, ECF No. 115-29.) This study received similar criticism. (*Id.*; Benoff Decl., Ex. AA at 352, ECF No. 115-30.) Nonetheless, Defendant continues to run its ads, now with updated claims that Onpro lowered the incidence of FN by 36% as compared to pegfilgrastim PFS based on its new study. (Benoff Decl., Ex. BB at 357, ECF No. 115-31.)

[1] A biosimilar product is "highly similar to [a] reference product notwithstanding minor differences in clinically inactive components" and bears "no clinically meaningful differences . . . in terms of the safety, purity, and potency of the product." 42 U.S.C. § 262(i)(2).

Defendant saw these ads as successful, as Defendant believed that the ads increased sales as well as convinced customers not to switch to biosimilars. (Benoff Decl., Ex. N at 268, ECF No. 115-17; Ex. MM at 897, ECF No. 115-42; NN at 907–08, ECF No. 115-43.)

C. The Impact on Ziextenzo

Plaintiff's Ziextenzo did not perform well at launch. The parties dispute the true cause of its poor performance, however. Defendant asserts that its advertising claims had no impact on Ziextenzo's sales because Defendant's ads did not refer to Plaintiff or Ziextenzo. (Akro. Decl., Ex. L at 182, ECF No. 116-13.) Moreover, Plaintiff has been unable to identify a single patient, prescriber, or insurer that would have used Ziextenzo but chose Onpro because of Defendant's advertising claims. (Akro. Decl., Ex. N at 229–33, ECF No. 116-15; Ex. G at 129–30, 131–36, 138–40, ECF No. 116-8; Ex. V at 322–23, 327–28, ECF No. 116-23.) Instead, Defendant argues that Ziextenzo performed poorly for four reasons unrelated to its advertising: (1) Ziextenzo was not the first biosimilar on the market; (2) Ziextenzo was not reimbursable by Medicare; (3) Ziextenzo was more expensive than both Onpro and its biosimilar competitors; and (4) the COVID-19 pandemic drove a higher demand for on-body injectors like Onpro because on-body injectors minimized patients' need to travel to healthcare facilities. (*See, e.g.*, Akro. Decl., Ex. H at 146 ¶ 13, ECF No. 116-9; Ex. L at 181; Ex. J at 167, ECF No. 116-11; Ex. M at 195, 199–200, 206–07, ECF No. 116-12.)

Plaintiff argues that while these reasons certainly impacted Ziextenzo's sales, Ziextenzo's poor performance was exacerbated by Defendant's advertising claims. According to Plaintiff's experts, Dr. DeForest McDuff and Dr. Matthew Perri, Defendant's advertising claims caused Plaintiff to lose more than $32 million in net profits, even after accounting for the four reasons above. (Benoff Decl., Ex. EE at 410, ECF No. 115-34; Ex. LL at 837, ECF No. 115-41.)

III. JUDICIAL STANDARD

Under Federal Rule of Civil Procedure 56(a), a court may grant summary judgment only if "there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). To prevail on a summary judgment motion, the movant must show that there are no genuine issues of material fact as to matters on which it has the burden of proof at trial. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). Upon such a showing, the Court may grant summary judgment on all or part of the claim. Fed. R. Civ. P. 56(a).

To defeat a summary judgment motion, the non-moving party may not merely rely on its pleadings or on conclusory statements. *See Celotex*, 477 U.S. at 324. Nor may the non-moving party

merely attack or discredit the moving party's evidence. *Nat'l Union Fire Ins. Co. v. Argonaut Ins. Co.*, 701 F.2d 95, 96–97 (9th Cir. 1983). The non-moving party must affirmatively present specific evidence sufficient to create a genuine issue of material fact for trial. *See Celotex*, 477 U.S. at 324. The materiality of a fact is determined by whether it might influence the outcome of the case based on the contours of the underlying substantive law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Disputes over such facts amount to genuine issues if a reasonable jury could resolve them in favor of the nonmoving party. *Id.*

IV. DISCUSSION

Plaintiff asserts claims for (1) false advertising under the Lanham Act, 15 U.S.C. § 1125(a); (2) false advertising under Cal. Bus. & Prof. Code §§ 17500, *et seq.*; and (3) unfair competition under Cal. Bus. & Prof. Code § 17200. Defendant moves for summary judgment on each claim, arguing that each claim fails because Plaintiff cannot prove it suffered an injury or a likelihood of future injury. The Court disagrees.

A. Lanham Act Claim

Under the Lanham Act, a plaintiff may seek damages, disgorgement of profits, and injunctive relief for false advertising. *Lexmark Intern., Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 135 (2014). For an award of damages or disgorgement, the plaintiff must prove that it suffered an injury caused by the defendant's false advertising. *Id.* For injunctive relief, the plaintiff must prove that the defendant's false advertising creates a likelihood of future injury. *Id.*

Defendant argues that Plaintiff cannot prove either an injury or likelihood of future injury sufficient to bring a claim for either damages and disgorgement or injunctive relief under the Lanham Act. The Court begins by assessing whether Plaintiff has demonstrated an injury.

1. *Injury*

A plaintiff may recover damages and disgorgement for false advertising under the Lanham Act only if it has been injured by the false advertising. A plaintiff may establish such an injury either by presenting "actual evidence of some injury resulting from the deception," or by demonstrating that the circumstances surrounding the parties and the advertising create a presumption of injury. *Harper House, Inc. v. Thomas Nelson, Inc.*, 889 F.2d 197, 210 (9th Cir. 1989); *TrafficSchool.com, Inc. v. Edriver, Inc.*, 653 F.3d 820, 831 (9th Cir. 2011).

In a suit between competitors, a plaintiff is injured by a defendant's false advertising if some consumers who would have purchased plaintiff's product instead purchased defendant's product because of defendant's false advertising. *TrafficSchool.com*, 653 F.3d at 825 (citing *Joint Stock Soc'y v. UDV N. Am., Inc.*, 266 F.3d 164, 177 (3d Cir. 2001)). Proving an injury through lost sales data can be challenging because lost sales are often "predicated on the independent decisions of third parties; *i.e.*, customers." *Id.* (quoting *Am. Soc'y of Travel Agents, Inc. v. Blumenthal*, 566 F.2d 145, 157 (D.C. Cir. 1977) (Bazelon, C.J., dissenting)). Thus, "[a] plaintiff who can't produce lost sales data may therefore establish an injury by creating a chain of inferences showing how defendant's false advertising could harm plaintiff's business." *Id.* Such an inference may be established through economic models using "actual market experience and *probable* market behavior." *Id.* (quoting *Adams v. Watson*, 10 F.3d 915, 923 (1st Cir. 1993) (emphasis in original)).

Defendant argues that Plaintiff has failed to present any direct evidence that it was injured by Defendant's allegedly false advertising. Indeed, Plaintiff fails to identify any patients, prescribers, or insurers who would have used Ziextenzo but instead chose Onpro because of Defendant's advertising. However, as explained above, Plaintiff need not present direct evidence to prevail on its claim. Rather, Plaintiff may provide evidence from which a jury could reasonably infer Plaintiff's injury, as it has done here.

Ziextenzo was among the handful of pegfilgrastim biosimilar PFS products on the market in late 2019. (Akro. Decl., Ex. D at 83–84.) After Ziextenzo was released, Defendant launched an allegedly false advertising campaign promoting Onpro as superior to pegfilgrastim PFS. (Benoff Decl., Ex. G at 146–47; Ex. H at 157–68.) According to Defendant's internal memoranda, the advertising campaign was designed to "optimally position Onpro in [the] face of biosimilar competition." (Benoff Decl., Ex. E at 123; *see also* Benoff Decl., Ex. D at 97 (noting Defendant's need for further studies to "[b]uild efficacy case for Onpro vs. Pegfilgrastim biosimilars"); Ex. F at 136 ("Promotional investments are needed to maintain Neulasta brand sales in a competitive market."); Ex. KK at 746, 771–72 (observing that the advertising campaign would lead healthcare providers to prescribe Onpro over PFS).) These ads ultimately succeeded, driving 89,000 additional units by Defendant's own estimates. (Benoff Decl., Ex. MM at 897.) Further, these ads convinced consumers not to switch from Onpro to competing biosimilars. (*See* Benoff Decl., Ex. N at 268 (noting that Defendant's "evidence generation" led a major insurer to reverse its decision to end its contract with Onpro); Benoff Decl., Ex. NN at 907–08, (noting that Defendant's advertising claims dissuaded a customer from switching to a biosimilar).) From these facts, a jury could reasonably infer that the entire pegfilgrastim biosimilar market lost sales as a direct result of Defendant's advertising. *See TrafficSchool.com*, 653 F.3d at 825–826 ("Sales gained by one are thus likely to come at the other's expense."). And, because Ziextenzo was one of those biosimilars, a jury could further infer that Ziextenzo lost sales, thereby causing Plaintiff an injury.

This inference is further corroborated by the reports Plaintiff's experts, Drs. McDuff and Perri, who opined that the entire biosimilar market suffered as a result of Defendant's advertising. (Benoff Decl., Ex. EE at 410; Ex. LL at 837.) In particular, McDuff opined that his economic models demonstrate that Plaintiff lost more than $32 million in net profits after Defendant launched its advertisements. (Benoff Decl., Ex. EE at 410.) Courts routinely find expert testimony sufficient evidence of an injury to survive summary judgment. *See, e.g.*, *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1146 (9th Cir. 1997) (citing *Brunswick Corp. v. Spinit Reel Co.*, 832 F.2d 513, 525 (10th Cir. 1987)). And economic analysis is a valid means of proving an injury caused by false advertising. *TrafficSchool.com*, 653 F.3d at 825.

Defendant points out, however, that Plaintiff's expert reports were unsworn and therefore inadmissible on summary judgment. *Shuffle Master, Inc. v. MP Games LLC*, 553 F. Supp. 2d 1202, 1210–11 (D. Nev. 2008) (citing Fed. R. Civ. P. 56(e)). However, on summary judgment, the court is only concerned with whether the evidence "could be presented in admissible form *at trial*." *McAfee v. Metro. Life Inc. Co.*, 368 Fed. Appx. 771, 772 n.1 (9th Cir. 2010) (emphasis added) (citing *Fraser v. Goodale*, 342 F.3d 1032, 1037 (9th Cir. 2003)). Accordingly, courts accept unsworn expert reports when there is no indication that the expert's testimony would be inadmissible at trial. *See, e.g.*, *Competitive Techs., Inc. v. Fujitsu Ltd.*, 333 F. Supp. 2d 858, 863 (N.D. Cal. 2004) (accepting unsworn expert reports on summary judgment); *Shinaburger v. United Aircraft Corp.*, 262 F. Supp. 52, 56 (D. Conn. 1966) ("the existence of such a statement, although not presently in evidentiary form, should alert the summary judgment court to the availability at the trial of the facts contained in the statement.").

To be sure, Defendant does offer additional arguments concerning the Plaintiff's expert's opinions. Particularly, Defendant questions how Dr. McDuff determined that Plaintiff's lost profits were caused by Defendant's advertising rather than other causes of Ziextenzo's poor performance. However, Dr. McDuff specifically accounted for these other causes in his economic models. (Benoff Decl., Ex. EE at 401.) To the extent Defendant argues that Dr. McDuff should have assigned more weight to these other causes, these arguments go more towards Dr. McDuff's credibility, not admissibility. Indeed, Defendant provides little argument for why either Dr. McDuff or Dr. Perri's expert opinions would be outright inadmissible at trial beyond hinting at its intent to file a *Daubert* motion. (Def.'s Reply at 7 n.16, ECF No. 113.) Absent a reason to believe that Drs. McDuff and Perri's opinions would be inadmissible, the Court finds it appropriate to consider their reports as further evidence of Plaintiff's injury so as to overcome summary judgment.

Thus, there is a genuine dispute of fact as to whether Plaintiff suffered an injury from Defendant's allegedly false advertising.

2. *Likelihood of Future Injury*

As explained above, Plaintiff has offered sufficient evidence to create a genuine dispute of fact as to its injury. Because the advertisements are ongoing, there is also a genuine dispute of fact as to the likelihood of future injury.

Thus, Plaintiff has presented sufficient evidence to create a genuine dispute of fact as to injury and likelihood of future injury necessary seek to damages, disgorgement, and injunctive relief under its Lanham Act claim. Accordingly, the Court **DENIES** Defendant's Motion as to Plaintiff's Lanham Act claim.

B. State Law Claims

To bring a claim for false advertising and unfair competition under California law, a plaintiff must prove it suffered an "economic injury" caused by the defendant's unlawful conduct. *Kwikset Corp. v. Super. Ct.*, 51 Cal. 4th 310, 321–22 (2011). An economic injury is more than a mere injury in fact; rather, it is "a loss or deprivation of money or property." *Id.* at 322.

As explained above, Plaintiff has offered evidence that it lost $32 million in profits as a result of Defendant's false advertising. (Benoff Decl., Ex. EE at 410.) Thus, Plaintiff has created a genuine dispute of fact as to whether it suffered an economic injury. Accordingly, the Court **DENIES** Defendant's Motion as to Plaintiff's state law claims.

V. CONCLUSION

For the foregoing reasons, the Court **DENIES** Defendant's Motion for Summary Judgment.

IT IS SO ORDERED.

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